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SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1996

**GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
AND MONSANTO COMPANY, *Petitioners,***

v.

**ROBERT K. JOINER AND KAREN P. JOINER,
*Respondents.***

**BRIEF OF PETER ORRIS, M.D., MPH,
DAVID OZONOFF, M.D., MPH,
JANET S. WEISS, M.D., and
OCAW (OIL, CHEMICAL & ATOMIC
WORKERS INT'L UNION, AFL-CIO)
AS *AMICI CURIAE*
IN SUPPORT OF RESPONDENTS**

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STATEMENT OF INTEREST OF AMICI CURIAE

Amici are physicians specializing in the field of preventive and occupational medicine (hereinafter, "occupational medicine"), as well as an international union composed of members who benefit from treatment by and consultation with those occupational medicine physicians who have devoted themselves to the understanding of the health problems affecting workers in modern society. Neither the physicians herein nor the Oil, Chemical and Atomic Workers International Union have any interest in the outcome of this lawsuit.¹ However, it is our understanding that the distinction between a trial court's review of the methodology of expert witnesses rather than an evaluation of the expert's conclusions is fundamental to this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2787 (1993). If that is so, then *amici* appear on their own behalf to alert this Court to the grave misunderstanding of the district court below relating to the methodology routinely employed by practitioners in the field of occupational medicine. If the flaws in the district court's methodological analysis are perpetuated, then *amici* fear that the rights of injured workers to gain proper redress will be unduly sacrificed. We believe that we are uniquely qualified to advise this Court on the proper methodology to be followed by occupational medicine professionals, because that is the field of our professional training. Lastly, before we endeavor to request that this court affirm the decision of the court of appeals or suggest where the district court erred in its understanding of the methodology utilized by occupational medicine professionals, we must confess that we are unqualified to offer this Court guidance concerning the intricacies of the legal issues presented

¹ More complete descriptions of *amici* are set forth in the appendix bound with this brief. Counsel for all parties have consented to the filing of this brief. Letters of consent are being filed with the Clerk. No counsel for any party authored any part of this brief, and no person other than *amici curiae*, its members as applicable, or their counsel made any monetary contribution to the preparation or submission of this brief.

by the petition for *certiorari* filed in this case.

SUMMARY OF ARGUMENT

In undertaking its duties pursuant to *Daubert* the district court misconstrued its role by attempting to evaluate the conclusions of Plaintiffs' experts rather than the methodology that they used. Not only did the district court fail to confine its role to evaluating the methodology used by Plaintiff's experts, but it also failed to understand the diagnostic methodology employed by occupational medicine professionals.

Occupational medicine is a distinct medical discipline which routinely requires practicing professionals to make judgments relating to conditions caused by chemical, occupational, and environmental exposures. The methodology used in making these judgments is differential diagnosis, which in the occupational medicine setting includes a clinical assessment, a toxicological assessment, an evaluation of all contributing factors, and then an assessment of the biological plausibility of any proposed explanation. In this effort to understand whether any hypothesized causative factor is biologically plausible, an occupational medicine professional may seek guidance from colleagues, *in vitro* studies, biophysical data, general scientific knowledge and experience, case reports, and case conferences, as well as research toxicology and epidemiology. None of these factors are exclusive and all are appropriately weighed within the overall matrix of understanding the proposed relationship.

The appropriate question for the district court below to have asked was: "Have Plaintiffs' experts used the proper methodology of their discipline to assess whether it is biologically plausible that Mr. Joiner's exposure to a carcinogenic mixture of dielectric fluids during the course of his occupation contributed in some way to his early manifestation of lung cancer at 37, even though the lung cancer was likely initiated by tobacco products?" Based upon the record before the district court, the answer would have had to have been in the affirmative. Whether it is "probable" is for the trier of fact to decide after full cross-examination and trial.

ARGUMENT

A. Basic facts relating to PCBs and the City of Thomasville

Pertinent to our understanding is a brief background of the facts as we understand them to be presented before the courts below. As stated by the district court, (36a), Appellant Monsanto manufactured polychlorinated biphenyls (PCBs) from approximately 1935 to 1977. Indeed, after 1945 Monsanto was the only manufacturer of PCBs in the United States. Appellants General Electric Company ("GE") and Westinghouse Electric Corporation ("Westinghouse") manufactured both electrical transformers and fire-resistant fluid. From the 1930s to the 1970s, both GE and Westinghouse marketed fire-resistant dielectrical fluid containing PCBs. GE's product carried the trade name "Pyranol," while Westinghouse's carried the trade name "Inerteen."

Throughout the time of Plaintiff Robert Joiner's employment all of the transformers which the City of Thomasville purchased from Defendants GE and Westinghouse used mineral oil-based dielectric fluid which was intended to be free of PCBs. However, beginning in 1983, the City of Thomasville discovered, via systematic testing, that the dielectric fluid in some of its transformers was contaminated with PCBs. From 1983 to 1993, the City tested approximately 2,668 of its transformers and determined that approximately half of the transformers tested showed PCB contamination.² Of these, about 2.5% contained very toxic levels of PCBs, i.e. above 500 parts per million ("ppm"), and about 16.7% contained hazardous levels above 50 ppm.³ The district court then concluded that

² According to the record below, there was also sufficient evidence for a jury to decide that dielectrical fluid in the transformers contained PCDFs and PCDDs. On the basis of the fact that issues related to these chemicals will likely be remanded to the trial court, their toxicology and carcinogenicity will not be discussed here.

³ The Administrator of the Environmental Protection Agency has determined that any substance containing concentrations of PCBs of 50 parts per million (ppm) or greater represents an unreasonable risk of injury to health within the United States. 40 C.F.R. Section 761.20 (1996).

"almost one out of every five (i.e., 19.2%) of the transformers the City tested presented a PCB hazard." (36a-37a)

The District Court also understood that, "with limited exceptions, Congress banned the production and sale of PCBs on January 1, 1978. 15 U.S.C. Section 2605(e)(2)(A). Congress took this action because in its view PCBs 'present an unreasonable risk of injury to health of the environment.' See 15 U.S.C. Section 2605(a)." This Court itself has noted that oil containing PCBs is a potent carcinogen. *Midlantic Nat'l Bank v. N.J. Dept. of Envtl. Prot.*, 474 U.S. 494, 497, (1986).⁴

Indeed, despite numerous decisions by Federal courts throughout the United States that PCBs are toxic and carcinogenic substances, the district court herein held that Plaintiffs "failed to show by a preponderance of proof that their experts' opinions regarding the PCB/lung cancer link are admissible under the standards set out in Rule 702 and explicated in *Daubert* at 68A." In coming to this drastic decision that Mr. Joiner should not be allowed to have a jury of his peers decide whether his toxic exposure contributed to his lung cancer, the district court, as will be shown, both utterly misconstrued the requirements of *Daubert* as well as the

methodology commonly utilized by occupational medicine professionals in making such assessments.

B. This Court's holding in *Daubert* and the standards for the testimony of experts

In June 1992, this Court in *Daubert* rejected the *Frye* "general acceptance" test for scientific evidence, (*id.* at 2792-94), and went on to make "some general observations" about proper admissibility analysis under Fed. R. Evid. 702. (*Id.* at 2796). In winding up its analysis, this Court explicitly addressed the narrow focus of Rule 702's scrutiny:

The inquiry envisioned by Rule 702 is, we emphasize, a flexible one. Its overarching subject is the scientific validity – and thus the evidentiary relevance and reliability – of the principles that underlie a proposed submission. The focus, of course, must be solely on the principles and methodology, not on the conclusions that they generate. (*Id.* at 2797) (footnote omitted).

As such, this Court separated the focus of Rule 702 on the distinction between the "principles and methodology" used by an expert, on the one hand, and the "conclusions" thereby reached by the expert. (*Id.* at 2797).⁵ Amici believe that this Court correctly understood that capable scientists may analyze the same body of data and reasonably arrive at diametrically opposed conclusions.⁶ However, this is not how the district

⁵ In the case of *Daubert*, Respondent (at 5) argued that the conclusion of plaintiffs' experts contradicts a "massive body of uniform scientific research" and (at 11) asserted the existence of an "overwhelming body of data that contradict their conclusion." This Court explicitly ignored Respondent's extensive factual arguments relating to the conclusions of plaintiffs' experts, treating them as irrelevant under Rule 702.

⁶ As scientists, we understand that it may be disquieting to non-scientists to see scientists on opposing sides disagreeing so markedly. This cuts against an implicit assumption that disagreement among scientists should be rare, because science is capable of objective, if not always experimental, verification. In fact, though, differences of opinion are quite common in science, but the arguments are spread out over many research papers and long time spans, and they are usually couched in

⁴ This Court's view of the highly toxic nature of PCBs is in accord with that determined by other circuit and Federal courts. *In Re Paoli R.R. Yard PCB Litig.* 35 F. 3d 717, 780 (3d Cir. 1994), cert. denied, 115 S. Ct. 1253 (1995) (noting "EPA thinks that PCBs have the same carcinogenic potency as vinyl chloride, which is one of only 14 chemicals that EPA has indicated have been proven to be carcinogenic by epidemiological studies"); *Dickerson, Inc., v. U.S.*, 875 F.2d 1577, 1583 (11th Cir. 1989) (recognizing the well-documented human health and environmental hazard of PCB exposure); *Potomac Elec. Power Co. v. Sachs*, 802 F.2d 1527, 1529 (4th Cir. 1986) (holding that PCBs are highly toxic materials); *Yaffe Iron & Metal Co., Inc. v. U.S.E.P.A.*, 774 F.2d 1008, 1010 n.1 (10th Cir. 1985) (holding that PCBs are extremely toxic to humans and wildlife, and pose carcinogenic and other risks to humans); *In the matter of Quanta Resources Corp.*, 739 F.2d 912, 913 n.1 (3d Cir. 1984) (finding that PCBs are extremely hazardous chemicals and are themselves toxic); *Environmental Defense Fund, Inc. v. Environmental Protection Agency*, 636 F.2d 1267, 1270-71 (D.C. Cir. 1980) (holding that PCBs are extremely toxic to humans and wildlife).

court understood its function. As stated by the court of appeals: "[i]nstead of viewing the bases of an expert's opinion as a whole to screen out mere speculation, the district court assessed only a portion of the studies relied upon by each of the Joiners' experts, and then excluded the testimony because it drew different conclusions from the research than did each of the experts." Indeed, the district court even states that it was persuaded by the Defendants' attack on "the conclusions that Plaintiffs' experts draw from the studies they cite." (67a) In evaluating these conclusions, the district court failed to understand that its role was to look at methodology and completely ignored the fact that this Court has dictated that the decision to allow such testimony should weigh broadly in favor of the proponent of the evidence, consistent with the liberal thrust of the Federal Rules of Evidence. *Daubert* at 2794.

As this brief will demonstrate, one of the fundamental problems in the district court's analysis is that it failed to determine exactly what the appropriate methodology is for experts in the field of occupational medicine, assuming instead that there is a scientifically fixed methodology to which all experts must subscribe. This is not the case. An epidemiologist engaged in the practice of observing large populations often will not make or does not feel capable of making judgments on

careful, if not polite, language. The underlying disagreements thus exist outside the courtroom as well as inside. It is only because, in a courtroom, time and space are compressed, and the nuances of language are erased in the adversary process that the disagreements appear so stark. (See *Hall v. Baxter Healthcare Corp.* 947 F. Supp. 1387, 1450 (D. 1996) where an independently appointed epidemiologist commissioned to evaluate the admissibility of the opinions of the plaintiffs' epidemiologist, Dr. Goldsmith, and the defendant's epidemiologist, Dr. Ory, concluded: "I believe there is sufficient scientific data upon which to base the opinions of both Dr. Goldsmith and Dr. Ory, the principal epidemiology witnesses, and I believe it would be appropriate to accept both of their testimonies. ... And it is even possible for reasonable epidemiologists to arrive at diametrically opposed conclusions, as do Drs. Ory and Dr. Goldsmith, with regards to the Hennekens study ...") (Emphasis added)

individual issues of causation. If such decisions are made, it is only through the process of inductive or deductive reasoning. The experimental toxicologist who conducts research on animals may not feel competent to extrapolate the results of animal testing "directly" to humans, and, if obliged to do so, may likely describe the medical condition at issue as being "consistent with" findings in animals. However, what the district court failed to appreciate is that there is a recognized field of medical practice whose members are physicians with special knowledge and training regarding the relationship between the sickness and injuries of individual patients and conditions of work, including the physical, chemical and psychological hazards of occupation. In this discipline, practicing professionals routinely make judgments on a regular basis relating to health concerns caused by chemical, occupational, and environmental exposure. In evaluating its assignment under *Daubert*, it is the methodology used in this field and the qualifications of its practitioners that the district court properly should have evaluated. *Amici* submit that Plaintiffs' experts are qualified practitioners in the field of occupational medicine and that they reasonably employed the appropriate methodology of their discipline in forming the opinions they had regarding the etiology of the onset of Mr. Joiner's lung cancer.

C. The qualifications of plaintiffs' experts

The Joiners' chief experts were Daniel T. Teitelbaum, M.D., and Arnold Schecter, M.D., M.P.H., both of whom are practitioners in the fields of preventive and occupational medicine and clinical toxicology. According to F.R.E. 702, the first requirement of an expert witness is that the witness must have sufficient capacity in his or her field by skill, experience, training, or education.

Dr. Schecter has substantial experience in the field of PCBs, PCDFs, and PCDDs, "having devoted the last ten years of [his] life to the study of dioxins, dibenzofurans and PCBs." (Affidavit of Arnold Schecter at 7:#18.H). He is a tenured full professor of medicine at SUNY Binghamton, having previously served on the faculty at the New Jersey Medical School, SUNY

Downstate Medical School and Harvard Medical School. At the time of his testimony, he had already published over 100 papers relating to dioxins, dibenzofurans and/or PCBs, many of which had been subjected to peer review, and were cited both by other researchers and the World Health Organization. In addition, Schechter served as a peer reviewer for the ATSDR for their Toxicological Profile documents on (a) PCBs, (b) dibenzofurans, and (c) dioxins. As director of the Broome County (New York) Health Department, he saw first-hand the public health consequences of PCBs, dibenzofurans and dioxins when he evaluated exposed residents after a major fire. He spends about ten percent of his current time seeing patients. (Dep. at 143:15; Schechter Aff. at 2:#5, 2-3:#6, 5:#14.) He has advised electric companies on PCB problems they have had (Aff. at 12) and done research on these chemicals in Vietnam, Russia, China, Cambodia, and the United States. (Dep. at 147:3-11)

According to the record, Plaintiffs' other medical expert, Dr. Teitelbaum is a practicing medical toxicologist and occupational medicine specialist in Denver, Colorado. He has been an adjunct professor of Environmental Science and Engineering Ecology at the Colorado School of Mines, teaching graduate toxicology courses in occupational and environmental toxicology. He also has been an associate clinical professor of medicine at the University of Colorado Health Sciences Center. He was a founder and former director of the Rocky Mountain Poison Control Center, and of the Physicians Poison Consultation Service at the University of Colorado Medical Center. He was a founder of the American Academy of Clinical Toxicology and the American Board of Medical Toxicology, serving as the first chairman of the examining board of the American Board of Medical Toxicology.⁷ Significantly, during the course of his clinical practice he has had substantial clinical experience in evaluating workers exposed to PCBs, having

⁷ Dr. Teitelbaum also taught two courses on the issues of toxicology and the epidemiology of toxic diseases at the Federal Judicial Center. (Aff. at 2)

interviewed, examined, and treated numerous patients who were employed in the electrical trades. (Aff. at 3)

According to the courts below, there was no question that both Drs. Schechter and Teitelbaum were qualified to testify as practitioners in the fields of preventive and occupational medicine.⁸ Indeed, given their vast experience in the area of PCBs it might even be argued that the threshold for the admissibility of their opinions should be lowered. (See *In re Paoli Railroad Yard Litigation*, at 742, noting that one factor to be considered in evaluating the admissibility of expert scientific

⁸ Defendants employed three experts who were well qualified in their individual disciplines, but none of these disciplines included preventive and occupational medicine or clinical toxicology, nor did their applicable experience include more than reviewing the literature of other scientists regarding the chemicals of concern in this litigation. William J. Waddell, M.D., an experimental toxicologist at the University of Louisville Medical School, while having testified in several cases regarding PCBs (Deposition at 25:10-13), ended his clinical practice at the end of his residency (*id.* at 28:9-19), is not licensed to practice medicine in Kentucky (*id.* at 29:7-9), had no training in occupational medicine or public health (*id.* at 33:16-19), and has never written on PCBs, PCDFs, or PCDDs (*id.* at 54:3-5). Defendants' second expert, Philip Cole, M.D., Dr. P.H., an epidemiologist, who, according to Petitioner, testified that "he knew of no scientist who believed that [PCBs cause small cell lung cancer]," J.A. 234-35, has also testified on several occasions regarding the health effects of PCBs (Deposition 25:9-12), but has not practiced clinical medicine since 1974 (*id.* at 31:20-26) and did not recall ever writing anything about PCBs, PCDFs, or PCDDs. (*id.* at 35:10-16). Lastly, William Charles Bailey, M.D., of the University of Alabama Medical School, a clinical pulmonary specialist with a subspecialty in asthma but not in occupational medicine or clinical toxicology, was not aware of ever treating a patient who had a PCB exposure (Deposition at 17:18-22), did not know what Inerteen (*id.* 24:25-26) or Pyranol (*id.* 25:1-5) even was, and had never written anything on PCBs or done any hands-on research in the field (25:12-16). This is not to argue that these experts are not qualified to testify but rather that a jury should properly be given the opportunity to evaluate their testimony in light of their applicable experience and that the court should understand that the methodology utilized by their disciplines may be different from the methodology appropriately utilized by occupational medicine professionals.

testimony is "the degree to which the expert testifying is qualified.") Moreover, what the district court failed to understand is that the discipline of occupational medicine employs its own well-recognized methodology and this methodology was the one used by both Drs. Schechter and Teitelbaum. The requirements of this methodology are mandated by the understanding of clinical practice. While epidemiologists and experimental toxicologists are not required to make individual judgments of causation and may even be subject to criticism if they do so, practitioners of occupational medicine must make such judgments on a regular basis and are criticized by their patients and peers if they don't or can't.

D. The methodology of differential diagnosis

The scientifically valid methodology employed by both Drs. Schechter and Teitelbaum is that of differential diagnosis. As will be delineated, each doctor reviewed Mr. Joiner's medical history, examined the records regarding his illness, personally interviewed or conducted a physical examination of Mr. Joiner, reviewed all information regarding putative agents which may be implicated in the etiology of his condition, and then, in light of the totality of the information known or acquired, employed the usual methodology of occupational medicine physicians in trying to determine the cause of their patients' injuries. Indeed, The Federal Judicial Center's *Reference Manual on Scientific Evidence* at 214 (West 1994) defines differential diagnosis as follows:

The method by which a physician determines what disease process has caused a patient's symptoms. The physician considers all relevant potential causes of the symptoms and then eliminates alternative causes based on a physical examination, clinical tests, and a thorough case history.

Harrison's Principles of Internal Medicine (8th edition, 1977) expresses it this way:

The clinical method always proceeds in a series of logical steps. The perceptive student will note certain similarities between the clinical method and the scientific method. Each begins with observational data which suggest a series of

hypotheses. The latter are tested in the light of further observations, some of which are made in the clinic and others in the laboratory. Finally, a conclusion is reached, which in science is called a *theory* and in medicine a *working diagnosis*.

It is thus clear that "differential diagnosis is a well-recognized, reliable method of medical diagnosis that has gained" widespread acceptance in the medical community and "... it is a method that involves assessing causation with respect to a particular individual." *In re Paoli R.R. Yard PCB Litigation*, at 758. Indeed, if one of the aims of *Daubert* was to ensure that experts use the same methodologies inside the courtroom as they use in their professional capacities outside of the courtroom, then differential diagnosis is plainly an appropriate methodology for scientific testimony if not the required methodology of practitioners of occupational medicine.

The first step taken by a physician in examining a patient and in attempting to come to a "differential" diagnosis is logically to make a clinical assessment of the patient, or as Dr. Teitelbaum described it, "a comprehensive and traditional occupational medical assessment of Mr. Joiner." (Aff. at 4). This is normally done through one or all of the following methodologies: 1) a review of the patient's chart, including, if possible, medical records from other treating physicians; 2) an interview with the patient in order to elicit a "history"; 3) a clinical examination of the patient; and 4) information from family members and co-workers regarding the patient's condition. The record is clear that both Drs. Teitelbaum and Schechter reviewed Mr. Joiner's medical records, personally conducted extensive interviews, and, in the form of depositions, gained information from family members and co-workers.⁹ Dr.

⁹Petitioners emphasize this in their brief (at 5), stating: "Dr. Schechter concededly had never examined him at all, and only once had even spoken to him, J.A. 103-05---in a lawyer's office, 'to get a feel for what kind of person he was, whether he was a person I would find believable.'"

In this recitation of the apparent facts, they neglect to cite from Dr. Schechter's affidavit where he fully describes the nature of his interview with Mr. Joiner: "A. I interviewed Robert Joiner and discussed with him

Teitelbaum carried out a comprehensive and traditional occupational medical assessment of Mr. Joiner,¹⁰ during the course of which he ascertained "Mr. Joiner's current clinical condition in order to understand the genesis of his lung cancer." (Aff. at 5) He also took an extensive medical history.

In undertaking their clinical assessment of Mr. Joiner, both Drs. Schechter and Teitelbaum also conducted a toxicological assessment. The goal of this assessment was to evaluate all potential factors in the etiology of the disease in question. As has been stated, inquiries were made into Mr. Joiner's family history, his social history, and his occupational history. Potential factors relating to his disease were identified and information was gathered relating to the nature, extent, frequency and duration of any toxic exposures he might have had which could possibly be implicated in his cancer diagnosis. At the same time efforts were made to exclude alternative explanations. (Schechter Aff. at 6-7:#18)

E. The role played by smoking

The logical first step in evaluating any case of lung

his general health, his medical history, his family medical history including but not limited to other victims of cancer, his exposure to potential carcinogens including but not limited to tobacco, his work history, and his specific tasks at work with special interest in his work involving transformer repair." As to physical examinations of Mr. Joiner himself, Dr. Schechter chose not to conduct an examination, "[b]ecause [Mr. Joiner] had a very thorough workup for his lung cancer and had been under intense medical care for a number of years when [he] saw him and [he] didn't want to put him through any more unnecessary hardship and [he] didn't feel the need for it." (Dep. of Schechter at 34:16-20)

¹⁰Petitioners in their brief before this Court (at 36) indicate that "Dr. Teitelbaum also had talked with respondent only once, also at the lawyers' office; without details he described what he did to be 'as complete an examination as one could do not working in one's own office.'" While it should not matter where the examination conducted by Dr. Teitelbaum took place, Dr. Teitelbaum's affidavit at 4 indicates that the examination took place in the offices of Northside Internists and Endocrinologists in Atlanta, Georgia.

cancer is, and was in this instance, to make a toxicological assessment of tobacco. As stated by *amicus*, Marcia Angell, (at 6) "cigarette smoking is so strong a risk factor for lung cancer [that it must be evaluated in any case of lung cancer] even though we do not yet know exactly how it [causes lung cancer]." By way of history and review of records, Drs. Teitelbaum and Schechter discovered that Mr. Joiner had previously smoked cigarettes for approximately eight years. For the first five to six years of his smoking, he smoked less than one pack per day, and during the last two to three years, he never smoked more than one pack per day. He quit smoking on April 4, 1982. His wife, Karen, never smoked, though he was exposed to second-hand smoke from his mother and father. In a review of his life and family history, it was revealed that lung cancer killed his mother and maternal uncle, leaving him genetically predisposed to developing the disease. On the basis of this information, both Drs. Schechter¹¹ and Teitelbaum concluded that it was more likely than not that Mr. Joiner's lung cancer was initiated¹² by exposure to tobacco products.¹³

¹¹Petitioners in their brief attempt to impeach Dr. Schechter by making it appear that in his deposition he admitted the connection between Mr. Joiner's smoking and his lung cancer, but that he deceived the court in his affidavit. They even note that "the Court of Appeals appeared unaware that in his deposition Dr. Schechter had conceded that... 'Mr. Joiner's lung cancer was equally linked to cigarette smoke and PCB exposure'" They accomplish this by quoting his affidavit out of context and leaving out the following statement: I believe that Robert Joiner's exposure to PCB contaminated mineral oil dielectric fluid served as a promotional effect on his lung cancer cells, probably initiated by cigarette exposure years before and caused him to contract lung cancer at the very young age of 37. (Affidavit of Dr. Schechter at 6:17)

¹²In cancer initiation, a minute change in the inheritable material of the cell (a mutation in the DNA) is reproduced each time the cell divides. If that initial alteration is such that the cell is changed from a normal to a malignant phenotype, then each of the progeny cells will also exhibit malignant behavior. After many cell divisions there may be a sufficient mass of malignant cells (a tumor) to disrupt the structure and function of the body and produce the symptoms and signs of the disease we call cancer. As stated by the district court, "The initiator can be any number of things including, but not limited to, tobacco smoke." (39a)

However, the question of causation which faces practitioners of occupational medicine rarely resolves simply. In this case in particular, some questions remained unanswered by the assumed connection between Mr. Joiner's lung cancer and tobacco. Although there definitely "was some risk of lung cancer [for Mr. Joiner] because he was a smoker ..., the likelihood of his developing lung cancer at age 37 on a statistical basis [would be] extremely small." (Aff. of Teitelbaum at 7-8; Aff. of Schecter at 6:#17) "If you compared the lung cancer rates at age 60, which are around 400 per 100,000 person years, with lung cancer rates in the 30's, which are almost too low to detect, somewhere around 10 to 15 per 100,000... it's pretty low risk, but it's there." (Aff. of Teitelbaum at 8) under these circumstances, the proper methodology for physicians specializing in occupational medicine would be to attempt to discern whether any other toxic exposure might reasonably have contributed to the early appearance of Mr. Joiner's cancer.¹³

¹³ If the putative agent of concern in this litigation were tobacco, one would guess that the *Daubert* analysis would not go any further and the differential diagnosis would have been sufficient to pass the district court's scrutiny without need to review epidemiological or toxicological data. This stems not from "general acceptance" in science but rather general acceptance of supposed "public knowledge." Though Dr. Teitelbaum himself subscribes to the belief that Mr. Joiner's lung cancer more likely than not was initiated by smoking, this opinion is based on the totality of the evidence and not statistical epidemiological analysis per se: "A remote smoking history of 8 pack years can only be considered a minimal risk factor for the causation of lung cancer. Such a history cannot be associated with any particular cell type of lung cancer. So few lung cancers at this age have been collected in the literature that no statistically meaningful analysis of histological type at age 37 is possible." (Teitelbaum Aff. at 8)

¹⁴ Both scientifically and legally there seems to be a fundamental misunderstanding by Petitioners and many amici as to what Drs. Teitelbaum and Schecter were attempting to articulate. For instance, *amicus*, Marcia Angell, at 5 states:

"Exposure to high levels of PCBs cannot be the sole cause of lung cancer, even if it plays some role, since people not so exposed also develop lung cancer. And exposure to high levels of PCBs do not invariably cause lung cancer, since most people so exposed remain healthy. Thus, the most that could be true is that PCBs may

F. Occupational exposure of Mr. Joiner

The logical first step in the analysis of occupational exposure was for Drs. Teitelbaum and Schecter to take extensive histories from Mr. Joiner and review testimony from co-workers and family members. As Mr. Joiner's job involved a substantial amount of time working on electrical transformers, a videotape of the working conditions of Mr. Joiner in repairing electrical transformers was viewed and the results of testing done on the transformers was evaluated. (Schecter Dep. at; see e.g. 16:10, 17:14-20, 18:8, 18:1-15, 33:4-13, 37:17-19)

Consistent with this review is the following summary of Mr. Joiner's work. (35a-37a) From the date of his being hired in 1973, Mr. Joiner was called upon to service transformers primarily when they had failed for one reason or another. The shop in which transformer repair was performed was below grade at the main offices of the electric company and had no forced ventilation, so and any vapors that were heavier than air remained in the workplace throughout the work day. When a transformer was in need of repair, Mr. Joiner would open it up,

contribute to lung cancer -- that is, they might be a "risk factor" (something that increases the *chance* of developing a disease)." (emphasis in the original)

But, this is precisely the point and exactly what Drs. Teitelbaum and Schecter are stating. The only material issue both scientifically and legally is whether defendants' products affected Mr. Joiner's body in a way so as to contribute to that lung cancer by accelerating it or promoting it. Under Georgia law, a plaintiff is not required to show that the defendant's tortious conduct was the sole, primary, or initiating cause of any of his injuries. In causes of action requiring medical proof of causation, it is enough for the plaintiff to show, to a "reasonable degree of medical certainty," *Parrott v. Chatham County Hosp. Auth.*, 145 Ga. App. 2d 269, 270 (1978); *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 743 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986), that a defendant's tortious conduct contributed to the mix of preexisting factors that together ultimately caused or, at minimum, accelerated his injuries. It is even immaterial whether defendants' products would have caused Joiner's lung cancer *absent* an alternative exposure to tobacco or whether he would have *eventually* developed cancer anyway. Georgia law protects Mr. Joiner from any tortious conduct that would cause him to develop lung cancer sooner than he otherwise would have.

drain out the dielectric fluid, bake the transformer dry, test the transformer for proper operation, make repairs, and then refill the transformer with fresh mineral oil dielectric fluid. The process of repairing transformers required that Mr. Joiner stick his hands into the dielectric fluid to perform necessary repairs and disassembles. The next step required the separation of the core of the transformer from the tank so that it could be dried, cleaned, inspected and repaired. This step also exposed Mr. Joiner to the dielectric fluid. In order to dry the transformer, a process called baking out was followed. During the baking out process, the dielectric fluid which was contained in the transformers was heated, to the point of smoking, for several days with football field lights until the core was dry. At no time were any precautions taken to prevent inhalation, ingestion, or absorption of the dielectric fluid.

The obvious conclusion drawn by Drs. Teitelbaum and Schecter from this information was that Mr. Joiner likely ingested, absorbed, and inhaled substantial quantities of PCBs from the fifty-three percent of the City of Thomasville's transformers that were contaminated. He ingested these when they splashed onto his face, or touched his hands to his mouth in any way; he inhaled them during the bake-out process when the football field lights were used to vaporize the dielectric fluids; and he absorbed them through his unprotected skin when he reached into the transformers to disable them while the dielectric fluid was still in the tank.

From the analysis of this occupational history, Drs. Teitelbaum and Schecter came to the conclusion that Mr. Joiner had been exposed to substantial quantities of PCBs,¹⁵ as well as

¹⁵Petitioners have pointed to the fact that when Mr. Joiner's blood was finally tested for PCB contamination many years after his exposure began that he only had levels that would be considered background, i.e. that "PCBs in small amount are detectable at 'normal' or 'background' levels in most human beings and animals in North America." Pet. Brf. at 2. First, to call levels "normal" or "background" is an interesting euphemism employed by the defendants who are aware that PCBs would not exist on this planet at all nor be inside each of our bodies if they had not been intentionally manufactured and marketed by companies such as

PCDF and PCDD contaminants, during the course of his work. At the same time they were aware that there is a substantial body of literature regarding the harmful effects of these chemicals."¹⁶ The question which they then faced is whether it was biologically plausible that Mr. Joiner's occupational exposure to PCBs had affected the disease process of his cancer.

G. Biological plausibility and coherence

At this point, the question properly raised by an occupational medicine professional is: "Was it biologically plausible that Mr. Joiner's heavy exposure to a likely carcinogenic mixture of dielectric fluids during the course of his occupation contributed in some way to the early manifestation at the age of 37 of his lung cancer?" In attempting to answer this question, the occupational medicine professional has no choice but to make a judgment -- to recognize that perfect congruence with the individual study question at hand and the limited fund of available information seldom permits one to be able to do more than extrapolate from all available evidence in

Petitioners herein. Further, the district court (42a) relied on Dr. Schecter's expertise in analyzing these samples:

"No study has been documented that examines subjects who have experienced weight loss associated with cancer, chemotherapy associated with cancer, and radiation therapy associated with cancer, as well as been subjected to excessive PCB, dioxin or dibenzofuran exposure. As a result, there is no control group to which Robert Joiner can be compared.... Adipose levels which are low do not mean that higher levels did not exist at earlier times. This is because PCBs are metabolized and excreted from the body over time."

In fact, Dr. Schecter stated at his deposition that what he found "remarkable about this man is after the weight loss and weight gain and severe cancer and cancer chemotherapy and radiation therapy, that his level [was] so high for him." (Dep. Dr. Schecter at 81).

¹⁶ One form of PCDD, TCDD, has recently been classified as one of the very few recognized "human carcinogens." This was announced in a press release on February 14, 1997 by the World Health Organization's International Agency for Research on Cancer (IARC). The conclusion was based on the fact that it was found that TCDD was "increasing the overall risk of lung cancer and all cancers combined."

order to evaluate an association. In conducting this evaluation, perhaps the first requirements of that analysis is whether the association is both "biologically plausible" and "coherent."¹⁷ As to "plausibility"¹⁸, the question specifically raised here is whether, given all that is known about Mr. Joiner's history, may the available scientific evidence lead one to believe that it is "plausible" that an association between Mr. Joiner's early manifestation of lung cancer and PCBs might exist? The second factor to be viewed is "coherence," i.e. does the putative association between Mr. Joiner's lung cancer seriously conflict with the generally known facts of the natural history and biology of the disease of lung cancer.

In attempting to arrive at an answer to these questions, the occupational medicine specialist has many sources of

¹⁷ In 1965 Sir Austin Bradford Hill offered nine viewpoints which he believed might be "consider[ed] before deciding that the most likely interpretation of it is causation." These were listed as: 1) strength of the association; 2) consistency of the association; 3) specificity of the association; 4) temporality; 5) biological gradient (dose-response); 6) plausibility; 7) coherence; 8) experiment; and 9) analogy. In laying out these "nine different viewpoints," he accompanied them with the following caution: "What I do not believe -- and this has been suggested -- is that we can usefully lay down some hard-and-fast rules of evidence that *must* be obeyed before we accept cause and effect. None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*. What they can do, with greater or less strength, is to help us to make up our minds on the fundamental question -- is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect." [299] "Plausibility" and "coherence" are singled out here, because they are factors which are evaluated before the review of the specific evidence or data sets is begun. (Sir Austin Bradford Hill, "The Environment and Disease: Association or Causation?" in *Proceedings of the Royal Society of Medicine*, 58:295-300 (1965)).

¹⁸ Sir Austin Bradford Hill does, however, indicate that "This is a feature I am convinced we cannot [always] demand. What is biologically plausible depends on the biological knowledge of the day. ... In short, the association we observe may be one new to science or medicine and we must not dismiss it too light-heartedly as just too odd. As Sherlock Holmes advised Dr. Watson, 'when you have eliminated the impossible, whatever remains, however improbable, must be the truth.'" *Id.* at 298.

information to sift through. For instance, Dr. Schecter knew from his toxicological assessment that Mr. Joiner likely was exposed to PCBs through inhalation and he knew from his experience as a scientist that PCBs "tend to accumulate in lung tissue." (Aff. at 7:#18J) Other types of information which might be available to an occupational medicine physician include, but are not limited to, discussions with colleagues, *in vitro* studies, biophysical data, general scientific knowledge and experience, case reports, and case conferences. Of course, they also include the observational work of epidemiologists and the experimental work of research toxicologists. But it must be cautioned that epidemiology and research toxicology, albeit very important, have their own limitations and should not be relied upon to the exclusion of all other evidence.

H. The use of observational human studies: epidemiology

If one were to compare differential diagnosis to a trial, one would describe clinical and toxicological assessment as direct evidence, while epidemiology (and research toxicology) would be akin to circumstantial evidence. By its very nature, epidemiology is not designed to answer questions of individual causation. As stated by *amicus*, Marcia Angell, "[e]pidemiologic studies yield information about probable risk factors in populations, not in individuals. They provide information about average risks in the average person in the population." (at 9D.) Moreover, epidemiological investigations are limited by the questions which are asked, i.e. the study protocol. Although a given study may be both well-designed and well-conducted, rarely can one expect the study question of an epidemiological investigation to be perfectly congruent with the question that is raised subsequently regarding an issue of individual causation. Indeed, even in the best of light, "[e]pidemiological studies are inherently capable of detecting only comparatively large increases in the relative risk. . . . Negative results cannot prove the absence of [risk]. . . ." *EPA Final Guidelines for Carcinogen Risk Assessment*, 51 Fed. Reg. 33992, 33995-96 (1986).

The subject of Mr. Joiner's exposure provides a perfect

example of the limitations of epidemiology in satisfactorily answering questions of individual causation. Prospectively, in order to answer this specific question an epidemiologist would prefer to have a study population of tens of thousands if not millions of workers who have been exposed to transformer dielectrical fluid and who smoke, and then to study the specific question of whether, for those who smoke and were exposed to PCBs there is a hastening in the mean date of diagnosis of small cell lung cancer (promotion) or a significant increase in the numbers of the study population ever so diagnosed (initiation). However, in the real world, time, money, and available study populations¹⁹ do not allow such questions to be asked, much less answered, with particularity to the facts of any specific incident of individual causation.

Despite these inherent limitations the district court inappropriately viewed epidemiology as a *sine qua non* for legal probability. Thus, the district court assigned to itself the role of scientist and endeavored with minimal information to analyze the studies presented to it. The district court weighed the evidence from Monsanto's own in-house study which, according to the district court, showed a risk of lung cancer that was three times greater than expected, (64a) but then accepted the conclusion of the defendants that it should be disregarded because it was not "statistically significant."²⁰ The district court then accepted

¹⁹ The obvious weakness of epidemiology is that we cannot experiment on humans so our study populations must come as we find them. In the case of PCBs, comparable study populations are not easily located. Monsanto has been the only manufacturer of PCBs in the United States since World War II which limits the number of studies that may be performed in this country on manufacturing cohorts. Moreover, since these chemicals are now ubiquitous in our environment, having been ingested by each and every one of us, it is impossible to find an unexposed control population.

²⁰ As expressed by the epidemiologist Kenneth Rothman in his *amicus* brief to this Court in *Daubert*, at 6.: "The result of using significance testing as the criterion for decision making is that the focus is changed from the information presented by the observations themselves to conjecture about the role chance *could* have played in bringing about those observations." [emphasis in original]. Rothman is the author of a

that the study by Bertazzi, et. al., *Cancer Mortality of Capacitor Manufacturing Workers*, in 11 *Am.J.Indus.Med.* 165 (1987), demonstrates an increase of lung cancer above expectations in PCB workers, but without even reading the study itself (63a n.27) rejected the study on the basis of Bertazzi's conclusion that although lung cancer deaths were above expectations, the risk estimate was not statistically significant and "such risk had never been suggested before" (63a) -- even though the district court knew that the risk had been suggested before by Monsanto's own in-house studies, which was apparently unknown to Bertazzi, et. al. The district court then discounts the study by Ronneberg, et al., *Mortality and Incidence of Cancer Among Oil Exposed Workers in a Norwegian Cable Manufacturing Company*, Part 2 Mortality and Cancer Incidence in 1953-84, in 45 *British J. Indus. Med.* 595, 601 (1988), regarding Norwegian cable workers, because the study, while definitely referring to a statistically significant increase in lung cancer among the exposed worker population, indicates that the cable workers were exposed to mineral oils but does not specifically define the nature of that exposure. (65a) The district court excluded this study knowing that PCBs were commonly found in such mineral oils (they were even found in the mineral oils of the City of Thomasville which were supposed to be free of PCBs) and that mineral oils themselves were the products sold by the Defendants to the City of Thomasville.

This is not to say that there is no merit at all to these individual criticisms directed to each such study by the defendants and the court. Indeed, the scientific method requires that all studies be critiqued. Furthermore, none of the studies were designed to answer the specific question raised by Mr. Joiner's cancer and inevitably every study may be faulted for its inability to answer such *sui generis* questions. For instance, in accepting the defendant's criticisms of the study by Ronneberg, the district court points out that the study was "confounded by

standard text, *Modern Epidemiology* (Little-Brown, 1986), and Editor-in-Chief of the journal *Epidemiology*.

... exposure to cigarette smoke." While in a typical study it would be expected that a researcher would attempt to exclude cigarette smoking as a risk factor,²¹ in the case of Mr. Joiner he would appropriately be a part of the study population of workers who both smoked and were exposed to PCBs.²²

When it is accepted that each epidemiological study -- and even the very best studies -- will be subjected to appropriate criticism as to the appropriateness of their application to issues of individual causation, then one can understand that the real question to be raised before this Court is who the proper entity is to evaluate these studies in light of the questions raised. The district court, obviously, assigned that responsibility to itself rather than to the jury. As stated by the court of appeals: "In ruling the Joiners' expert testimony inadmissible, ... the district court... accepted defendants' criticisms of the conclusions reached in those studies, stating that 'the studies simply do not support the experts' position that PCBs *more probably than not* promoted Joiner's lung cancer.'²³ (at 12a, emphasis in the

²¹ The Ronneberg study does indicate that the results cannot be accounted for by excess smoking alone.

²² As Dr. Teitelbaum stated in his Affidavit at p. 22: "A study of considerable importance to Mr. Joiner's case appeared in the British Journal of Industrial Medicine in 1988, in two parts. These papers by Ronneberg and colleagues, investigated the mortality and incidence of cancer among oil exposed workers in a Norwegian cable manufacturing company. In Part 2, the mortality and cancer incidence study between 1953-84, a statistically significant excess of deaths from lung cancer in transformer oil exposed workers was observed. Ten deaths from lung cancer were observed where 3.9 were expected. Nine of the cases of lung cancer occurred 20 or more years after first employment, where 2.7 would have been expected yielding a P value of 0.01, a highly significant result."

²³ Without explanation the district court also failed to review a number of the studies relied upon by Drs. Teitelbaum and Schecter. As is stated by the court of appeals: In addition, each doctor utilized numerous scientific studies and authorities. Although the district court apparently considered only four epidemiological studies and two animal studies, Teitelbaum referred to several additional studies which he utilized in forming his views. Among those not mentioned by the district court were

original)

If the assignment given by this Court to the trial court is to render its own independent opinion on each and every piece of scientific evidence, then there is not a single piece of evidence that cannot be ably and properly criticized as not providing a fit for the question of individual causation at hand. For instance, the trial court speaks of the need for proof not just of lung cancer but of small cell lung cancer. (53a) However, if evidence of small cell lung cancer is the appropriate judicial criteria, then the reliance on epidemiology will likely lead to a methodological impasse: in conducting a mortality study where data regarding cause of death is normally based upon diagnosis on death certificates, it will be difficult if not impossible to define a relationship of a putative carcinogen to small cell lung cancer in particular, as death certificates rarely define death more particularly than lung cancer. Indeed, any review of the literature to achieve a perfect fit will inevitably be reduced to the absurd. In the case of Mr. Joiner, if the fit required of epidemiological studies is that of small cell lung cancer in 37 year old men in Thomasville who smoked but were never exposed to any carcinogens other than PCBs, then one can readily see that no applicable epidemiological study could ever answer the question posed.

studies by researchers Gustavsson and Hogsted, findings of the International Program on Chemical Safety ("IPCS") World health Organization Criterion, and 'a whole series of [epidemiological studies] listed in [the World Health Organization] document.'

Similarly, in addition to the studies mentioned in the district court's opinion, Schecter relied, in part, upon 'recent work such as that of Dr. George Lucier and colleagues at the National Institute of Health,' 'IARC studies, International Agency on Cancer at the World Health Organization,' studies by 'Dr. James Huff of the National Institute of Health,' the Zober and Theiss studies from Germany, and also Manz's study on European workers... In this case, the Joiners' experts discussed the studies of at least thirteen different researchers, and referred to several reports of the World Health Organization that address the question of whether PCBs cause cancer."

I. The use of animal studies

When an occupational medicine professional reviews animal studies, the search similarly is for biological plausibility, i.e. does the research toxicology aid in the overall conclusion of a plausible association. This is because, in theory, experimental studies are designed to demonstrate a biologically plausible mechanism by which injury could occur, as the existence of such an effect in other species or test systems may reasonably aid in explaining what has been observed in humans upon whom such tests cannot be performed. See E. K. Silbergeld, *The Role of Toxicology in Causation: A Scientific Perspective*, in 1 *Courts, Health Science & the Law* 374, 381 (1991).

Obviously, though, just as with epidemiology, there are limitations to the use of animal studies when it comes to evaluating issues of individual causation. For instance, unless the study is performed to replicate the particular individual human experience (and then it will be subjected to criticism for being the product of litigation), it is unlikely that existing animal studies will closely recreate all of the conditions upon which issues of individual causation rest. However, this does not mean that we should ignore the results of animal studies "since animals may differ from people in their response," as is indicated by *amicus* Marcia Angell at 8. Even Petitioners' own expert, Dr. William J. Waddell, indicates that using animals to extrapolate to humans "is accepted and is appropriate and proper." (Deposition of Waddell at 32:14-15)

As is evidenced in virtually all federal regulations dealing with toxic risk assessments, experimental data based on studies of animals are a critical element of the process of assessing the nature and extent of health risks associated with chemical and other exposures and in attempting to comprehend the relationship between exposures and certain adverse outcomes in humans.²⁴ In the courtroom, in the governmental regulatory process, and in science generally these studies all serve the same

²⁴ See, e.g., 42 Fed. Reg. 6532 (1977) (proposed and final discharge standards for PCBs based on animal carcinogenicity).

purpose. They do not demonstrate actual causation themselves, but, if "plausible," they allow us to draw reasonable inferences from their results. If an experimental animal study demonstrates a mechanism for carcinogenicity, then it both makes it more plausible that the same will occur in the human model and it elucidates for us a possible mechanism of action for our evaluation.

In this sense, the district court and various *amici* have seemed to misconstrue what was gained from the animal experimentation in the Anderson studies.²⁵ *Amici curiae*, Bruce N. Ames, *et al.*, (at 18) support the decision of the trial court to reject the studies on the basis that: "[t]he animal studies plaintiffs' experts relied upon were not indicative of a link between PCB exposure and Joiner's type of cancer because the conditions of the mice (huge doses, direct injection, use of initiator chemicals) were not similar to the nature of Joiner's exposure - his 'dose' was far smaller, and plaintiffs' experts have not identified an 'initiator'." Those tests did not mimic human exposures." Obviously, it is easily recognized that there was hardly complete congruence between these experimental studies and Mr. Joiner's specific exposure. Given the practical

²⁵ Of course, there are other animal studies which have displayed the carcinogenic properties of PCBs. "Based on the observations of liver tumors in several studies of rats fed various commercial mixtures of PCBs in the diet and on suggestive evidence for carcinogenicity in humans (reviewed in (ATSDR) (1992)). *Draft Toxicological Profile for Polychlorinated Biphenyls*. (U.S. EPA) (1994). *Integrated Risk Information System (IRIS)*. The U.S. EPA has classified PCB mixtures as probable human carcinogens." Vater, *et. al.*, *A Case Study of Cancer Data Set Combinations for PCBs*, in *Regulatory Toxicology and Pharmacology*, 22:2 (1995)

²⁶ Of course, this is not entirely accurate, as both Drs. Teitelbaum and Schechter assert that the "initiator" was cigarette smoke. Moreover, specificity, which seems to be required by these *amici*, is not an absolute for causal inference. Indeed, even for cigarette smoke, there is no *a priori* method to predict exactly which sites will be affected in a particular species, or perhaps even in an individual. Cigarettes will cause lung cancer in one person, bladder cancer in another, emphysema in a third, and leave another relatively unharmed.

requirements of animal experimentations it would be shocking if there was. The point of these studies seems to be missed. The fact that the studies did demonstrate an increase of lung tumors related to PCBs makes it more "plausible" that Mr. Joiner's lung cancer may be related to his PCB exposure. Whether it makes it more "probable" is hopefully, for the jury to decide.

J. The proper legal test of scientific conclusions is cross-examination

Ultimately, the determination of the proper methodology to use and the evidence to consider depends on the question which is being asked. Petitioners and the *amici* who support Petitioners seek the trial court to answer the following question: "Does the available toxicological and epidemiological data on PCBs more probably than not to a reasonable degree of medical certainty support the conclusion that PCBs cause small cell lung cancer so that that testimony may be presented to the jury?" They support the district court when it answered "no" to this question. Yet, for the district court to answer this question necessarily required that it make a factual determination regarding the evidence presented to it. We believe that the district court was really answering the wrong question. The question that it needed to address was: "Have Plaintiffs' experts used the proper methodology of their discipline to assess whether it is biologically *plausible* that Mr. Joiner's heavy exposure to a carcinogenic mixture of dielectric fluids during the course of his occupation contributed in some way to his early manifestation of lung cancer at the age of 37, even though his lung cancer was likely initiated by cigarette smoke?" To this question, on the basis of the very same epidemiological and toxicological evidence, the trial court should answer "yes" without having to evaluate the actual conclusions being drawn by the experts from the data they rely upon. As the D.C. Circuit has explained, "there is nothing in *Daubert* to suggest that judges become scientific experts, much less evaluators of the persuasiveness of an expert's conclusion." *Ambrosini v. Labarraque*, 101 F.3d 129, 134 (D.C. Cir. 1996), *cert. dismissed*, 117 S. Ct. 1572 (1997).

The further question of "whether it was more probable than not" is properly left to the jury to decide. And the proper technique to be utilized by the opponents of Plaintiff's position to challenge that conclusion is through cross-examination rather than motions to the court for relief.²⁷

It is in this sense that *amici* herein agree with what this Court stated in *Daubert*:

"[C]ross-examination, presentation of contrary evidence, and careful instruction on the burden of proof, rather than wholesale exclusion ... is the appropriate means by which evidence based on valid principles may be challenged. (at 5d) In this regard respondent seems to us to be overly pessimistic about the capabilities of the jury and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." (at 13 III.)

Most fundamentally, this Court has emphasized over and over again that the role of the jury may not be denigrated through the use of "trial on affidavits"²⁸ as was true in the within case before the district court. "Credibility determinations, the

²⁷ Ultimately, we must look at why there is such a substantial controversy over the use of observational epidemiology and research toxicology, and why Petitioners and their *amici* urge that the district court review these studies in detail in the absence of clinical evaluation, occupational assessment, or a medical professional's differential diagnosis. In other words, why are Petitioners so ardently defending the right of the district court to prevent a jury from undertaking a review of the evidence presented. Is it that they feel that jurors are incompetent to make such evidentiary determinations? Is it that they are fearful that jurors might be duped by misinformation? Or is it that they are afraid that jurors will conclude that their products caused or contributed to the injuries alleged?

²⁸ This comment is especially relevant to the case below. As the district court admitted: "With one exception, neither party has provided the court with a copy of the studies cited in the briefs The court, for the most part, has had to rely on the excerpts from the studies that the parties have provided in their briefs." (63a n.27)

weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Indeed, it is the very "purpose of the jury...to sort out the true testimony from the false, the important matters from the unimportant matters, and, when called upon to do so, to give greater credence to one party's expert witnesses than another's. Such matters occur routinely in the American Judicial system, both civil and criminal." *Barefoot v. Estelle*, 463 U.S. 880, 902 (1983) (citation omitted). This Court has indicated that "the opportunity for cross-examination . . . is critical for ensuring the integrity of the fact-finding process. Cross-examination is "the principal means by which the believability of a witness and the truth of his testimony are tested." Indeed, cross-examination is the "greatest legal engine ever invented for the discovery of truth." *Kentucky v. Stinger*, 482 U.S. 730, 736 (1987).

Petitioners underestimate the value of cross-examination in the context of a trial in which all of the evidence is before the trier of fact, whether it be judge or jury. Cross-examination often subjects a witness to scrutiny that is longer-lasting, more intense, and more extensive in the breadth of subjects examined than most any process occurring within the course of scientific debate. First, there are rarely time limits placed on cross-examination itself. Second, once on the witness stand, a witness may be obliged to endure a line-by-line scrutiny of any article or evidence the witness seeks to rely upon, being required to explain and defend every point. Third, the questions asked on cross-examination are not limited to the specific parameters of the paper or report that is the foundation of the expert's conclusion; instead, almost anything the expert has done, said, or written is open to examination. For example, on cross-examination an expert witness can be subject to close questioning not only on the basis of the specific sources of his or her testimony, but can be impeached by anything he or she had said or written that is potentially inconsistent. His or her motives and credentials can be scrutinized in ways unimaginable to peer review editors, referees, conference organizers, and colleagues.

K. An expert's opinions should rely on the totality of the evidence reasonably considered

In conclusion, it is our view that the appellate court correctly concluded that: "[o]pinions of any kind are derived from individual pieces of evidence, each of which by itself might not be conclusive, but when viewed in their entirety are the building blocks of a perfectly reasonable conclusion." It is only through assessing the entirety of the evidence in the context of the injured worker's circumstances that an occupational medicine professional can properly evaluate causation. Data cannot be micro-managed; it must be reviewed in context and as a part of the totality of the evidence. Clearly, all forms of scientific data are subject to criticism on one ground or another, but that does not preclude valid judgments and determinations regarding causation if the various approaches are used with an understanding of their power and their limitations.²⁹ As stated by Sir Austin Bradford Hill:

All scientific work is incomplete - whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time. ... [I]n passing from association to causation I believe in 'real life' we shall have to consider what flows from that decision. On scientific grounds we should do no such thing. The evidence is there to be judged on its merits and the judgment (in that sense) should be utterly independent of what hangs upon it - or who hangs because of it. But in another and more practical sense we may surely ask what is involved in our decision. In occupational medicine our object is usually to take action. If this be operative cause and that be

²⁹ Marcia Angell, an epidemiologist, in her *amicus brief* at 20 agrees with this in principle: "In reaching a decision about causation, the crucial consideration is the totality of evidence. (Citation omitted) Each study should be considered as part of a mosaic of information that taken together yields the answer to a scientific question."

deleterious effect, then we shall wish to intervene to abolish or reduce death or disease. (Bradford Hill at 295, 300 (1965)).

Amici submit that it is at the core of the very nature of our judicial system that we should do no less. Statutes of limitations and repose can place an equally severe time constraint on the ability of injured workers to gain redress. The need for proper medical intervention and the payment of medical bills will not wait. For ever more complete information or better, more particularized studies. If the evidence to be submitted is biologically plausible, if the methodology used in gathering that evidence is that used by practitioners in the field, then it should be submitted to the trier of fact. Otherwise, the newly framed and individualized *Daubert* approach portends severe inequity for injured claimants, as litigants with similar complaints may be subjected by different "gatekeeping" judges to substantially different evidentiary standards and validation processes.³⁰

CONCLUSION

The judgment of the court of appeals should be affirmed.
Respectfully submitted.

GERSON H. SMOGER
Counsel of Record

³⁰ On this basis, this Court's review of the question presented is perhaps the most important question which could be addressed. In trial courts throughout the country motions based upon *Daubert*, if successful, invariably result in the granting of summary judgment. An appellate court reviewing a decision to exclude testimony is almost always reviewing the dismissal of the entire underlying claim. If this Court accepts the standard of review of these decisions as being an abuse of discretion or, worse, clearly erroneous, then it is issuing a salvo in favor of the trial judge rather than the jury as the true trier of fact. In very real terms, four separate judges have now reviewed the evidence presented by Drs. Teitelbaum and Schechter. Two found that it should be presented to the jury and two found that it shouldn't -- is there any better reason than this to state that the powers of the jury should not be usurped?

APPENDIX

The Oil, Chemical & Atomic Workers Intl. Union (OCAW) is an organization representing more than 90,000 men and women. Although OCAW was originally founded to represent oil and chemical workers, who still make up the majority of its membership, the union has grown to include workers in a wide range of energy, chemical, pharmaceutical, and allied industries.

Peter Orris received his MPH degree from Yale University in 1970 and his M.D. from Chicago Medical School in 1975. He is licensed to practice medicine in the state of Illinois and is a Diplomat of the American Board of Preventive Medicine in Occupational Medicine. Currently he has appointments as the medical director of Corporate Health Services, Northwest and as Professor of Preventive and Internal Medicine at Rush University College of Medicine. He also serves as Director of the Health Hazard Evaluation Program, University of Illinois School of Public Health and Illinois Department of Health; as the director of Research and Interdisciplinary Projects, Great Lakes Center for Occupational and Environmental Health and Safety, University of Illinois School of Public Health; and as an attending physician, Division of Occupational Medicine, Cook County Hospital. Among his many publications, he has written on the health effects of PCBs.

David Ozonoff received his M.D. degree from Cornell University Medical College in 1967 and his MPH from Johns Hopkins School of Hygiene and Public Health in 1968. In 1977 he became the first chair of Boston University's Department of Environmental Health in the new School of Public Health (a position he still holds). He currently holds the rank of Professor in the School of Public Health and Professor in the School of Medicine. His research work centers on health effects to communities of various kinds of toxic exposures, especially from hazardous waste sites; new approaches to understanding the results of small case-control studies; and the effects of exposure misclassification in environmental epidemiology. He has been principal or co-investigator of a number of major studies of waste sites, including the Silresim Superfund site and a large

case-control cancer study on Otis Air Force Base. He is currently the Principal Investigator of a Cooperative Agreement between Association of Schools of Public Health and ATSDR studying data needs for health assessment around DOE sites. He is also the Director of the Superfund Basic Research Center, a multidisciplinary effort to understand basic scientific problems connected with the Federal Superfund Program, funded by the National Institute of Environmental Health Sciences. In addition, he is the Medical Director of the Boston Environmental Hazards Center, a joint effort of the Department of Environmental Health and the Boston Veterans Administration Medical Center.

Janet S. Weiss received her M.D. in 1979 from Jefferson Medical College in Philadelphia, PA with honors in medicine and pathology. She is a Diplomate of the American Board of Medical Toxicology, a Diplomate of the American Board of Preventive Medicine in Occupational Medicine and Medical Toxicology, a Diplomate of the American Board of Pathology and a Diplomate of the American Board of Toxicology. She is an Assistant Clinical Professor of Medicine at the University of California, San Francisco's Department of Occupational and Environmental Medicine, and has consulted widely on issues of occupational medicine and medical toxicology for numerous governments, medical clinics, and pharmaceutical companies while maintaining a private practice in clinical toxicology. She has an extensive publication history in medical surveillance for occupational and environmental hazards.